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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,831	12/21/2001	Paul Richard Vaughan	Q-67867	4805
23373	7590	07/31/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,831

Applicant(s)

VAUGHAN ET AL.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 12 May 2006 in response to the Non-Final Office Action mailed 14 November 2005. Claims 31-35 were considered in the 14 November Office Action. Claim 31 was amended and claim 36 was added in the 12 May Paper. Claims 31-36 are presently pending and under consideration.

Response to Amendments and Arguments

Claim Rejections - 35 USC § 112, first paragraph

Rejection of claims 31-33 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendments thereto.

Rejection of claims 31-35 under 35 U.S.C. 112, first paragraph, as containing impermissible new matter is withdrawn in view of the amendment to claim 31.

Claim Rejections - 35 USC § 102

Claims 31-35 stand rejected and newly added claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by St. Pierre *et al.* U.S. Patent No. 5,856,308 (filed 27 September 1996) for the reasons of record and herein below in the response to Applicant's arguments.

Response to arguments

In response to the *prima facie* rejection and arguments of record, Applicant first contends that it is clear from the teachings of St. Pierre et al. that the "polymer" heterologous to collagen

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added to the triple helical protein is to be activated and grafted onto, *inter alia*, the peptide strands. Applicant urges, “[T]here is no teaching or suggestion in [the passage cited in Applicant’s remarks] of recombinantly producing both the collagen mimic and the polymer.” (12 May Paper, p. 8.)

This argument has been fully considered but is not deemed persuasive. It is first noted that the claims have been amended such that the invention now encompasses embodiments wherein both “m” and “o” of the equation set forth in claim 31 are 0 (i.e., the protein does not comprise a peptide domain that is heterologous to collagen proteins). Even if one were to accept Applicant’s assertion that the teachings of St. Pierre et al. with regard to recombinant expression are limited only to expression of a core domain of repeating amino acid triads, *arguendo*, that embodiment is now within the scope of the claims and, for at least that reason, the amended claims are anticipated by the recombinantly expressed core domain of St. Pierre et al.

Furthermore, the instant claims are directed to a product and, therefore, read on the product produced by any means. Even if, as Applicant alleges, St. Pierre is only teaching producing a core domain of repeating amino acid triads with subsequent addition of the polymer by chemical means, the ultimate product of this process, absent some evidence to the contrary, is the same as the product produced by a method wherein the entire molecule is expressed recombinantly. In other words, the recitation “recombinant” in the claims is viewed as a process limitation that defines the product only insofar as the product must be structurally the same as a product produced by the process of recombinant expression. As a polypeptide comprising a core domain of repeating amino acid triads fused to a polyglutamic acid, polyaspartic acid or polylysine as taught by Pierre et al. would be structurally the same regardless of whether it is

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produced by a process that involves chemical fusion or a process that involves recombinant expression of the entire protein, the polypeptide anticipates the polypeptide of the instant claims regardless of the method by which it is produced.

Next, Applicant, while acknowledging that St. Pierre et al. teaches that the polymer can be a peptide selected from polyglutamic acid, polyaspartic acid and polylysine, urges that St. Pierre et al. teaches that polymers such as polyethylene glycol are particularly suitable for clinical use. (P. 8, 3rd full ¶ through p. 9, 1st full ¶.)

This argument has been fully considered but is not deemed persuasive. Even if St. Pierre et al. does teach some alternative embodiments as preferred, that does not negate the teaching that the polymer can be an amino acid sequence, which could be produced by recombinant means. The fact is that St. Pierre et al. teaches synthetic hydroxylated triple helical proteins comprising polymer domains that are polyamino acid chains, which anticipate the claimed invention irrespective of additional teachings of alternative constructs.

Finally, Applicant contends that, insofar as St. Pierre et al. suggests recombinant production of the core, the reference provides no details on how to produce the core recombinantly. In particular, Applicant contends that St. Pierre is completely silent on the need to ensure that there is hydroxylation and Applicant disagrees with the Examiner's contention that hydroxylation would be inherent.

This argument has been fully considered but is not deemed persuasive. Applicant provides no evidence that one of ordinary skill in the art would have required more guidance than what is presented in St. Pierre et al. to express a polypeptide recombinantly. In fact, in 1996 recombinant expression of polypeptides was routine in the art. St. Pierre et al. teaches

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embodiments wherein X_{bb} of the tripeptide repeat is hydroxyproline as most preferred. (See especially col. 4, ll. 52-53.) Given the teaching that hydroxylated prolines are most preferred the skilled artisan would recognize expression systems wherein prolines are hydroxylated as among those that are suitable. Furthermore, as St. Pierre et al. teaches a protein having the same structure as the polypeptide of the instant claims, it makes no difference whether the prolines are hydroxylated in the cell during recombinant expression or at some point after recombinant expression. What is critical to anticipation of a product is whether the art teaches a product that is structurally the same as the product claimed, not the means by which the product is produced.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §102(e) as anticipated by the art.

With regard to claim 36, which recites that the recombinant hydroxylated triple helical protein comprises "an exogenous biologically active domain(s)", the limitation "exogenous" is not limiting without a specific reference to an organism, cell, etc. from which the exogenous domain is distinguished. (See *infra*.) In other words, reciting that a domain is "exogenous" in the absence of a clear reference point means only that the domain is different, and, as all peptide domains are exogenous to something, all peptide domains can be considered "exogenous".

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is directed to a recombinant hydroxylated triple helical protein comprising “an exogenous biologically active domain(s)”. The term “exogenous” is relative, literally meaning, “Originating or produced outside of the organism”. (Stedman’s Medical Dictionary online.) Thus, without some specific reference to the organism to which the domain is exogenous, it is not possible to ascertain the metes and bounds of the claim limitation. Therefore, the metes and bounds of the claims as a whole are indefinite.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Daniel M. Sullivan, Ph.D.

Primary Examiner

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